



Current Landscape: Value Assessment Frameworks

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About the National Pharmaceutical Council

The National Pharmaceutical Council is a health policy research organization dedicated to the advancement of good evidence and science, and to fostering an environment in the United States that supports medical innovation. Founded in 1953 and supported by the nation's major research-based pharmaceutical companies, NPC focuses on research development, information dissemination, and education on the critical issues of evidence, innovation and the value of medicines for patients. For more information, visit www.npcnow.org and follow NPC on Twitter @npcnow.



Key Observations and Highlights

- Value assessment tools can be one of many important inputs that health care decision-makers consider when making complex decisions related to health care services and treatments.
- Now that value assessment frameworks are being used more often in health care decision-making, it is critically important that decision-makers consider the strengths and limitations associated with each framework.
- This analysis reviewed seven U.S. value assessment frameworks across six broad categories: development process, measures of benefit, measures of cost, methodology, evidence and assessment process.
- A reflection on the review raises several areas of caution where there is room for improvement among the frameworks, including:
 - **LACK OF PATIENT-CENTEREDNESS** - Frameworks should incorporate the elements that matter most to patients. Patients' clinical characteristics and preferences vary considerably, and therefore assessments of value should not be one-size-fits-all.
 - **LACK OF TRANSPARENCY** - To ensure the validity and credibility of value assessments, framework methodologies and models should be fully transparent and reproducible.
 - **LIMITED EVIDENCE BASE** - All high-quality evidence, including real-world evidence, should be incorporated into assessments, and assessments should be updated regularly as new evidence becomes available.
 - **UNTESTED METHODS** - It is crucial that frameworks' underlying methodologies are sound and validated, and their potential impact on patients is understood.
 - **CONFUSING OUTPUT** - Value assessment outputs can be confusing or misleading to end users. Misinterpretation of a value assessment's output could result in a health care decision that is misinformed or erroneous at best, or harmful to the patient at worst.
 - **LACK OF SYSTEM-WIDE PERSPECTIVE** - Moving to value-based health care requires a comprehensive focus on all health care components. Value assessments should be conducted for a broad range of treatments and health care services, rather than focusing primarily on drugs.
- There is no "best" framework and they all have strengths and limitations. A conscientious user will rely on multiple frameworks and tools to assess value rather than looking to a single framework to inform health care decisions.





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Acronym Glossary

Acronym	Full Name
ACC	American College of Cardiology
AHA	American Heart Association
ASCO	American Society of Clinical Oncology
CEA	Cost-effectiveness analysis
CEVA	Center for Enhanced Value Assessment
COP	Categories of Preference
EB	Evidence Blocks
ICER	Institute for Clinical and Economic Review
IVI	Innovation and Value Initiative
MCDA	Multi-criteria decision analysis
NCCN	National Comprehensive Cancer Network
OS	Overall survival
OSVP	Open-Source Value Project
PAVE	Patient-Driven Values in Healthcare Evaluation
PFS	Progression-free survival
PPVF	Patient-Perspective Value Framework
PValue	Center for Pharmaceutical Value
QALY	Quality-adjusted life year
QHES	Quality of Health Economic Studies
QoL	Quality of life
RCT	Randomized controlled trial
SDM	Shared decision-making



Background

As the U.S. health system shifts from one driven by the volume of health care services to one focused on the value of health care that is provided, there has been an increased emphasis on measuring value. Focusing on value can enable efficient use of our resources, incentivizing use of high-value services and treatments and discouraging the use of low-value services. To facilitate this shift to a value-based health care system, some stakeholders have developed frameworks to measure value.

In June 2016, we published a landscape assessment that compared and contrasted five U.S. value assessment frameworks. The original landscape assessment included frameworks by the American College of Cardiology and the American Heart Association (ACC-AHA), the American Society of Clinical Oncology (ASCO), the Institute for Clinical and Economic Review (ICER), Memorial Sloan Kettering Cancer Center (DrugAbacus), and the National Comprehensive Cancer Network (NCCN).

There has been significant evolution in the field of value assessment since June 2016. First, new frameworks have emerged, including the Innovation and Value Initiative's (IVI) Open-Source Value Project (OSVP) and the Patient-Perspective Value Framework (PPFV) developed jointly by Avalere and FasterCures. Second, several organizations have released resources on value assessment best practices to help promote evidence-based methods and patient-centeredness in value frameworks. Third, new value centers have been founded to develop new tools and methods for assessing value, including the Research Consortium for Health Care Value Assessment, Patient-Driven Values in Healthcare Evaluation (PAVE), Center for Enhanced Value Assessment (CEVA) and Center for Pharmaceutical Value (PValue). Fourth, some framework developers have made substantial changes to their assessment processes, methodologies and outputs. Finally, as the field of value assessment has matured, some frameworks are now being used to inform health care decision-making.

Frameworks have now become more influential in determining two types of health care decisions. At the patient level, frameworks can influence the therapies that are chosen by patients and their doctors. At the payer level, frameworks can influence whether and how therapies will be covered and reimbursed, impacting patient access to needed treatments. Given this change in the decision-making landscape and the potential for significant impact on patient access, it remains critical to assess if these frameworks have been developed with adequate rigor.

As value assessment becomes more ingrained in health care decision-making, it's important to be aware of how these frameworks differ and their respective strengths and limitations. By comparing and contrasting these frameworks in their current forms, we can have a more informed dialogue about what elements should be included in a value framework, how those elements should be measured, and how a value assessment should be conducted and utilized for health care decision-making.

Methodology

This update to our landscape assessment builds upon our previous analysis of the five primary U.S. value assessment frameworks, which were reviewed at a high level by Neumann and Cohen¹ as well as the ISPOR Task Force on Value Assessment.² We have included two additional value frameworks that were developed since this analysis was last updated (Table 1). These frameworks include:


- The American College of Cardiology and the American Heart Association (ACC-AHA) Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures, which aims “to include cost-effectiveness/value assessments and recommendations in practice guidelines and performance measures.”³
- The Conceptual Framework to Assess the Value of Cancer Treatment Options, developed by the American Society of Clinical Oncology (ASCO) with the goal of providing a “standardized approach to assist physicians and patients in assessing the value of a new drug treatment for cancer as compared with one or several prevailing standards of care.”⁴ An updated version of this framework was released in May 2016; all references to the ASCO framework in this document refer to this updated version, sometimes referred to as ASCO 2.0.⁵

Table 1: Summary of Landscape Analysis Updates

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
Original Landscape (June 2016)	Conceptual framework included; no assessments had been made	Framework version 2.0 included	Online tool included	Core framework included	n/a	Evidence Blocks (EB) included	n/a
Updated Landscape (Spring 2020)	Greater detail has been added now that value assessments have been incorporated in some guidelines	No updates since original landscape	No updates since original landscape	2017 framework revisions and modifications for ultra-rare diseases; 2020-2023 framework revisions have been added	New entrant added to landscape	2017 Categories of Preference (COP) have been added	New entrant added to landscape



- Memorial Sloan Kettering Cancer Center's DrugAbacus (DrugAbacus), created by Peter B. Bach, MD, MAPP, as "a first draft of a tool that could be used to determine appropriate prices for cancer drugs based on what experts tend to list as possible components of a drug's value."⁶
- The Institute for Clinical and Economic Review (ICER) Value Framework, primarily intended for insurers, aims "to form the backbone of rigorous, transparent evidence reports that, as a basis for broader stakeholder and public engagement, will help the United States evolve toward a health care system that provides sustainable access to high-value care for all patients."⁷ An updated version of the framework for 2020-2023 was released in January 2020.⁸ A modified version of the framework for ultra-rare diseases (URD) was released in November 2017 and updated in January 2020.⁹ A modified version of the framework for single or short-term transformative therapies (SST) was released in November 2019.¹⁰
- The Innovation and Value Initiative (IVI) Open-Source Value Project (OSVP), which offers "a transparent and open-source system for estimating the value of medical technologies in a way that centers on the patient, allows for a broad range of perspectives, incorporates the latest available evidence, and considers the full range of scientifically defensible approaches."¹¹ IVI does not promote a specific framework or a singular method of assessing value, but rather provides a testing ground for new methods and model design. The customizable nature of their models enables the user to adapt the framework design and inputs. Descriptions of the IVI framework in this document broadly include all available considerations, but the user may elect to exclude or change these considerations to suit their preferences and localized decision needs.
- The National Comprehensive Cancer Network (NCCN) Evidence Blocks (EB), which are "intended as a visual representation of five key measures that provide important information about specific recommendations contained within the NCCN Clinical Practice Guidelines in Oncology. ... The goal is to provide the health care provider and the patient information to make informed choices when selecting systemic therapies based upon measures related to treatment, supporting data, and cost."¹² In 2017, NCCN began incorporating Categories of Preference (COP) within its Guidelines, which aim to "provide guidance on which recommendations within the NCCN Guidelines are optimal, while providing a range of recommendations to accommodate a variety of clinical circumstances."¹³ NCCN also has a Framework for Resource Stratification of NCCN Guidelines that can be used in "low and middle income countries (LMCs) where certain diagnostic tests and/or treatment approaches may be unavailable."¹⁴ Because this landscape assessment is focused exclusively on value assessment in the United States, this second NCCN framework is not included in this analysis. All references to the NCCN framework throughout this analysis pertain to both the EBs and the COPs unless otherwise stated.

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- The Patient-Perspective Value Framework (PPVF), created by Avalere and FasterCures to offer a new way to “assess the value of health care services that considers factors that matter to patients – such as functional and cognitive status, symptom relief, complexity of regimen and medical as well as non-medical out-of-pocket costs to the patient and family – and weights them in accordance with assessed patient preferences.”¹⁵

Our original landscape analysis built on the work of Neumann and Cohen by providing additional detailed observations and delving deeper into the rather disparate frameworks. This analysis has been updated to include the new entrants to the field of value assessment and to reflect modifications made to existing frameworks.

This analysis includes the same six broad categories that were identified in the original landscape assessment: the framework development process, measures of benefit, measures of cost, methodology, evidence and the framework assessment process. Within each category we identified key components for evaluation and populated table shells with those key components.

We contacted all seven framework developers to share that we were updating our landscape analysis. Representatives from DrugAbacus and ASCO reported that no updates had been made to their respective frameworks since the previous publication of this analysis in 2016. For the remaining five frameworks, we followed the same protocol from the original paper: we initially assessed each framework internally to revise and fill in the table shells, then sent the draft tables to the framework developers. Representatives from all five reviewed the tables to fill in missing information and make corrections. The tables in this paper reflect updates – if any – that each framework has incorporated since the previous publication of this analysis.



Overview of Frameworks and Intended Purposes

The seven value assessment frameworks have varying purposes, generally reflecting the interests and expertise of the developing organizations (Table 2). As professional societies with physician members, ACC-AHA, ASCO, and NCCN designed their frameworks to assist with shared decision-making between patients and physicians. ICER, IVI, the PPVF and DrugAbacus are intended for broader audiences — payers, policy makers, physicians and patients — although the ICER and DrugAbacus frameworks are generally perceived as payer tools.

ASCO, NCCN, and DrugAbacus all have an oncologic focus; ACC-AHA has a cardiovascular one, while ICER, IVI and PPVF have no limitations on the types of treatments that could be assessed. The frameworks are generally focused on drugs or drug regimens, although there has been limited use of ICER and ACC-AHA to evaluate other medical services, and most of the other frameworks could theoretically be extended to other treatments beyond drugs.

The format and output vary greatly among these frameworks:

- ACC-AHA assigns one of four value levels to a treatment — high, medium, low, uncertain.
- ASCO calculates a “net health benefit score” and separately reports cost.
- DrugAbacus calculates a preference-weighted price that represents the user’s weighted preferences and estimated monthly costs.
- ICER’s assessments have three value outputs: a cost-effectiveness analysis (CEA) output, a health-benefit price benchmark (formerly called a value-based price benchmark), and an assessment of long-term value for money. The CEA output estimates the incremental cost for an additional quality-adjusted life year (QALY) relative to a comparator. The health-benefit price benchmark represents the price that would be needed for a treatment to meet a specific cost/QALY threshold. Long-term value for money is assigned a value of high, medium, low or uncertain based on panel opinion. Reports also include an inventory list of other benefits/disadvantages and contextual considerations. ICER also estimates potential national budget impact for a treatment and will issue an “Affordability and Access Alert” in its final report if the relevant estimate is above a spending threshold created by ICER.
- IVI generates both a CEA and a multi-criteria decision analysis (MCDA) output. The CEA represents the user’s weighted preferences for a treatment relative to a comparator and provides an

Table 2: Overview of Value Assessment Frameworks

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
Target Audience	Clinicians/ patients	Clinicians/ patients	Primarily payers; secondarily policy makers, clinicians, patients	Primarily payers; secondarily policy makers, clinicians, patients	Payers, policy makers, clinicians, patients	Clinicians, patients	Payers, policy makers, clinicians, patients
Services Addressed	Drugs, devices, other interventions	Drugs	Drugs	Primarily drugs, limited extension to other medical services	Drugs (could be extended to other health care services)	Treatment regimens, primarily drugs	Drugs (could be extended to other health care services)
Conditions Addressed	Cardiovascular	Oncologic	Oncologic	All conditions, particular focus on new drugs anticipated to be high impact	All conditions	Oncologic	All conditions
What Is the “Value” Output	Value statement based on cost- effectiveness (high, medium, low, uncertain)	Numerical net health benefit score; drug regimen cost	Preference- weighted price	CEA results (cost per QALY gained), health-benefit price benchmark assessment of long-term value for money (high/ intermediate/ low); inventory list of other benefits/ disadvantages and contextual considerations	Summary of patient outcomes, CEA results (cost per QALY gained), MCDA results (preference- weighted value score)	EBs: score (1-5) for each of five evidence blocks (efficacy, safety, quality of evidence, consistency of evidence, affordability); COPs: hierarchically categorizes treatments into three tiers (preferred intervention, other recommended intervention, useful in certain circumstances)	Preference- weighted scores for each of five domains (patient preferences, patient- centered outcomes, patient and family cost considerations, quality and applicability of evidence, usability and transparency)



assessment of incremental QALYs, incremental costs, an incremental cost-effectiveness ratio, and a conclusion of whether the treatment is cost-effective based on the user's weighted preferences and reported willingness to pay per QALY. The MCDA output reflects overall value of a treatment on a 0-100 common scale based on user-generated MCDA weights.

- NCCN presents five-by-five visual Evidence Blocks (EBs) representing Efficacy, Safety, Quality of Evidence, Consistency of Evidence and Affordability. The blocks are filled in according to scores from 1-5, with 5 being the best. Categories of Preference (COPs) are presented as a counterpart to the EBs, and hierarchically categorize treatments as "preferred intervention," "other recommended intervention" and "useful in certain circumstances."
- PPVF's scoring methodology weighs patient preferences to generate preference-weighted scores within each of five domains: Patient Preferences, Patient-Centered Outcomes, Patient and Family Cost Considerations, Quality and Applicability of Evidence, and Usability and Transparency.

Value assessments from ACC-AHA and NCCN are included in guidelines issued by the organizations, while ICER's assessments are issued as public reports. DrugAbacus and IVI's OSVP are both online tools through which the user generates preference-weighted output. The PPVF is not a stand-alone tool; it is intended to be incorporated into other applications such as collaborations with other frameworks or shared decision-making tools, including the PPVF-driven shared decision-making tool for patients with advanced breast cancer.¹⁶ Similarly, ASCO will ultimately use its framework to populate a tool for shared decision-making.

Development of Frameworks

Development details are publicly available for most, but not all, of the frameworks (Table 3).


Table 3: Development of Framework

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
Who Developed It?	Writing committee (primarily physicians)	ASCO Value in Cancer Care Task Force (physicians)	Peter Bach/ Real Endpoints	ICER	IVI in consultation with academic partners and disease specialists	NCCN staff in consultation with disease specialist clinicians	Avalere and FasterCures
How Inclusive Was Development?	Unknown	Advisory committee including oncologists, patient advocates, payers and biopharmaceutical industry provided input	Unknown	Advisory committee of payers, patient organizations, physician organizations and biopharmaceutical industry provided input for the initial framework; framework updates have had similar broad input and public comment	A clinical scientific advisor, provider groups and patients provide input on each OSVP model	Restricted to NCCN members per NCCN regulatory requirements	A multi-organization steering committee informed the development of the framework
Was There a Public Comment Period?	Unknown	Yes	Unknown	Yes – framework is opened to public comment and updated periodically	Each OSVP model has a public comment period and accepts comments on an ongoing basis	NCCN accepts comments on an ongoing basis	Yes

Table 3: Development of Framework *(continued)*

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
Was It User Tested?	Unknown	Software tool will be user tested prior to release	Unknown	Payers used the original framework and provided feedback; ongoing framework use by stakeholders informs future updates	User interfaces for all models included user testing by patient and clinician stakeholders; user interviews occurred to assess functional aspects valued by each group	Yes	Framework-driven shared decision-making tool for advanced breast cancer was user tested
How Often Will the Framework Be Updated?	Unknown	The framework was last updated in 2016, with no additional updates planned	No updates are planned	Every two to three years	Initial updates are planned within 12-18 months after public comment on the model. Subsequent updates will depend on new evidence generation, user need and resources	The processes are regularly reviewed to determine if changes are needed	Unknown

- The ASCO framework was developed by the “ASCO Value in Cancer Care Task Force,” composed of physicians. They sought input from an advisory committee that included oncologists, patient advocates, payers and the biopharmaceutical industry, and followed that input with a public comment period; the ASCO framework reflects changes made in response to these comments.
- The ICER framework was developed by ICER staff, who also sought input from an advisory committee consisting of payers, patient organizations, physician organizations and biopharmaceutical manufacturers. Updates to the framework have been informed by ICER’s Methods Advisory Group, a public meeting and broad stakeholder input via public comment.

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- IVI's OSVP models were developed by IVI staff and academic partners in conjunction with a clinical scientific advisor with relevant disease-specific expertise. IVI also contacted patient and provider groups during initial model development.
 - The NCCN framework was developed by NCCN staff in consultation with disease specialist clinicians. Per NCCN regulatory requirements, development was restricted to NCCN members, but they accept public comments on the framework on an ongoing basis.
 - The PPVF was developed by Avalere and FasterCures in collaboration with a multi-stakeholder steering committee, along with input from patient groups, life science companies, payers and policy experts.

Full details are unknown for DrugAbacus and ACC-AHA. The five frameworks with known development details all held, or have ongoing, public comment periods.

The extent and type of user testing varies across the frameworks. ASCO has plans to user test its framework after its software tool has been developed. NCCN beta tested its framework. ICER had several payers utilize its original framework and provide feedback, and ongoing framework use by stakeholders informs future updates. IVI conducted user testing of OSVP interfaces with patient and clinician stakeholders, including interviews to assess the functional aspects valued by each group. Avalere user tested an application of the PPVF framework, a shared decision-making tool for advanced breast cancer.

Elements of Frameworks

In this section we consider four general framework elements: benefits, costs, methodology and evidence. Each framework incorporates these elements in different ways.

A. Framework Components of Value: Benefits

Benefits are a primary component for a measurement of value. However, benefits can be defined and measured in many different ways (Table 4). The various frameworks each include some measure of efficacy/effectiveness and safety, but they differ in how they are measured and incorporated. For ACC-AHA, IVI, ICER and PPVF, these measures will vary by condition or treatment.

Table 4: Benefits

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
How Is Efficacy/Effectiveness Measured?	Varies by condition	Improvement in overall survival/ progression-free survival/ response rate (hierarchical, hazard ratio preferred); bonus for palliation of symptoms/ treatment-free interval/tail of the curve survival/quality of life	Improvement in overall survival or surrogate	Varies by condition	Varies by condition	Average of panel members' assessment of effectiveness in prolonging life, arresting disease progression or reducing symptoms	Varies by condition
How Is Safety/Risk Measured?	Varies by condition	Relative frequency of grade 1-4 toxicities; adjustment for unresolved toxicities one year post-treatment	Frequency and severity of side effects (grade 3 or 4) relative to side effects that would otherwise be experienced	Varies by condition	Varies by condition	Average of panel members' assessment of likelihood of/ severity of side effects	Varies by condition (but addresses frequency, severity, duration of side effects/ complications, discontinuation rates)

Table 4: Benefits (continued)

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
Inclusion of Patient-Centric Metrics (e.g., Quality of Life)	QoL embedded in CEA from the literature; depending on available literature, guidelines may also include a discussion on QoL (separate from value assessment)	Yes, bonus points for QoL	No	QoL embedded in CEA, other benefits/ disadvantages and contextual considerations are included qualitatively	Yes, embedded in CEA and optionally in MCDA	No	Yes
Inclusion of Indirect Benefits (e.g., productivity)	No	No	No	Yes, in quantitative sensitivity analysis; can be included qualitatively in long-term value for money voting	Yes	No	Yes
Inclusion of Unmet Need	Qualitatively	No	Yes	Qualitatively	No	No	No
Inclusion of Burden of Illness	No	No	Yes	Qualitatively	No	No	Yes
Credit for Innovation	No	No	Yes	Qualitatively	No	No	No
Time Horizon for Clinical Measurement	Dependent upon available literature	Dependent on endpoint assessed in relevant clinical trials	Treatment duration	Generally lifetime horizon, occasionally a shorter horizon is estimated	Varies based on user preference (can be simulated over a particular time period or over a lifetime)	Varies with disease site	Varies by condition




Although ASCO, DrugAbacus and NCCN share an oncologic focus, their efficacy/effectiveness measures are somewhat different.

- ASCO uses a hierarchy for measure selection, beginning with improvement in overall survival (OS), followed by improvement in progression-free survival (PFS, if OS is not available) or response rate (if OS and PFS are not available). For both OS and PFS, use of a hazard ratio is preferred to a median measure. A hazard ratio measures survival at any given point in time for the treatment group relative to the control group. This provides a more complete picture of relative efficacy than simply looking at median survival. ASCO also awards bonus points for “tail of the curve” survival (i.e., greater potential for long-term survival), palliation of symptoms, improved quality of life (QoL) and treatment-free intervals.
- DrugAbacus measures improvement in overall survival or a surrogate measure if overall survival data is not available.
- NCCN uses the average of panel members’ quantitative assessment of effectiveness in prolonging life, arresting disease progression or reducing symptoms.

The oncologic frameworks also measure safety somewhat differently. ASCO uses the relative frequency of grade 1 through 4 toxicities, with an adjustment for unresolved treatment-related (symptomatic) toxicities one year after treatment completion. DrugAbacus considers the frequency and severity of grade 3 or 4 side effects, relative to side effects that would otherwise be experienced. NCCN averages panel members’ assessment of the likelihood or severity of side effects.

While patients care about how well a treatment works and what side effects they are likely to experience, they also care about factors such as their QoL and ability to work productively. Some patients will value unmet need – a treatment for a condition that previously had none. Some will value reduced caregiver burden. High burden of illness is another factor for consideration, as is innovation (e.g., novel mechanism of action or a therapy for patients who previously had no treatments available). Inclusion of these patient-centric factors varies across the frameworks.

- ACC-AHA includes unmet need as a value factor, albeit in a qualitative manner. QoL is embedded in CEA from the literature. When the literature allows, a discussion of QoL is also included in the guidelines (separate from the value assessment).
- ASCO includes bonus points for QoL.
- DrugAbacus includes unmet need, burden of illness and innovation, all in a quantitative manner.

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- ICER includes QoL, which is embedded in its CEA output. Other benefits/disadvantages and contextual considerations are evaluated qualitatively through a likert-scale vote, which means the quantitative assessment outputs (CEA results and health-benefit price benchmark) are unchanged by their inclusion. However, the qualitative output (long-term value for money categorization) could be impacted by this information, depending on how panel members incorporate it into their voting decisions. When feasible, ICER includes productivity in a quantitative manner, but has historically done so in a sensitivity analysis, leaving the primary quantitative assessment outputs unchanged (alternate outputs calculated in the body of the report). With the 2020-2023 framework, when the impact of the societal factors is substantial, ICER will promote the societal perspective to a co-base case (alternate outputs are reported alongside the primary outputs). For the URD framework, select factors (patient and caregiver productivity, education, disability and nursing home costs) can be included in a quantitative manner if evidence is available to support the inclusion.
 - IVI's models to date include productivity and QoL in a quantitative manner.
 - NCCN does not include patient factors in the estimation of EBs or COPs.
 - PPVF includes QoL, productivity and burden of illness in a quantitative manner.

In addition, patients care about the time horizon of benefits, ideally measuring benefit over the course of their entire life. The time horizon varies for the various frameworks, and even within a given framework it depends on such parameters as the disease site (e.g., breast cancer, colon cancer) or clinical trial endpoint. IVI allows users to assess lifetime benefit and ICER assesses lifetime benefit when the evidence allows it.

B. Framework Components of Value: Cost

Cost can be incorporated in a framework and measured in a variety of ways (Table 5). ASCO, NCCN and PPVF keep cost as a separate factor in their assessments. ACC-AHA and ICER use cost as part of a CEA to calculate the cost in dollars to gain an additional QALY. IVI models include cost in both the CEA and MCDA assessments. DrugAbacus reports cost as a comparator for a user-generated value assessment. ICER is the sole framework to use cost to calculate a national budget impact estimate.


The way costs are measured and what costs are measured also varies considerably.

- ACC-AHA uses existing health economic literature in its assessments, so any cost estimates are specific to the literature from which they were drawn, as is any inclusion of cost offsets.

Table 5: Costs

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
How Is Cost Included?	As part of a CEA in previously published literature	Reported separately	As a comparator for user-generated value assessment	As part of a CEA; as part of a scenario tool to estimate national budget impact	As part of CEA and MCDA for user-generated value assessment	EBs: Reported separately; COPs: only included when regimens are judged to be clinically equivalent and the difference in cost is significant	Reported separately as one of five domains
How Is Cost Measured?	Drawn from relevant health economic literature	Drug acquisition cost; patient copayment	Actual cost to Medicare	Net price for interventions; Medicare fee schedules for other costs; a human capital approach is used to calculate productivity costs	Drug acquisition and administration costs (minus an estimated rebate), general management and monitoring costs, adverse event costs, hospitalization costs, and productivity losses	Panel members' assessment of overall cost	Comprehensively defined out-of-pocket medical costs, nonmedical costs and future costs of care (see text for more detail)
Are Medical Cost Offsets Included?	Depends upon available literature	No	No	Yes	No	No	No

- ASCO uses drug acquisition cost in the framework to estimate the cost of the entire drug regimen (including anti-cancer therapy and required supportive care) and plans to use patient copayment amount in the software tool it is developing.
- DrugAbacus uses actual cost to Medicare to estimate the monthly cost of a drug.
- In 2017, ICER revised its framework to measure treatment cost using net price (price net of discounts, rebates and other price concessions) rather than a publicly available list price. Medical cost offsets are estimated using the Medicare fee schedule and productivity costs are based on a human capital estimation approach.

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- IVI relies on existing health economic literature to inform its estimates of hospitalization costs and productivity loss. Drug acquisition and administrative costs are based on wholesale acquisition cost (WAC) data less an estimated rebate.
 - NCCN includes a view of the total cost of the full episode of care, based on the average of panel members' assessment of overall cost.
 - PPVF scoring methodology focuses on the overall costs to patients and their families associated with different health care options, including out-of-pocket costs to the patient (supportive care agents and device maintenance), non-medical costs (costs associated with travel, child/elder care, supportive care, required lifestyle/behavioral change, patient and family work productivity/lost wages, patient and family education/skill building, required hours of caregiving, complexity of patient support, administrative burden) and future costs of care (subsequent health care utilization and changes in costs of therapies).

C. Framework Methodology

Most of the frameworks have created new (and untested) methodologies for assessing value or are using an untested combination of new and established methodologies (Table 6). The exception is ACC-AHA, which draws from literature using established methods.

DrugAbacus, IVI and the PPVF incorporate weights into their methodologies, enabling users to customize the assessment to represent their personal preferences. ASCO intends to include weights in the tool it is developing to allow for a similar type of preference customization by the user (e.g., preference for length of survival over avoidance of adverse events). The NCCN EB includes scores for five different factors; users could choose to give preference to specific factors in their decision-making, implicitly creating customization. ACC-AHA and ICER do not include customization, although ICER is currently developing a customization option.

Transparency and replicability vary across the frameworks.

- ACC-AHA is based on previously conducted health economic assessments from a literature search, making them both transparent and replicable.
- ASCO's example assessments are presented in a transparent and replicable manner.
- DrugAbacus' assessment equation is transparent, but the underlying data are not accessible to the user. Without the underlying data, replication outside of the online tool is difficult.



Table 6: Methodology

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
Use of Accepted Methodology	Draws from literature that uses established methods	New methods	New methods	Combination of established and new methods	Combination of established and new methods	New methods	New methods
Ability for User to Customize Assessment	No	Weights will be present in final tool	Yes	Not currently, but in development	Yes	EBs: User can give preference to certain blocks in decision-making; COPs: No	Yes
Transparency and Replicability of Assessment	Framework and assessments for value statements are transparent and replicable	Assessment examples are transparent and replicable	Assessment equation is transparent but underlying data are not accessible	Assessment models can be shared with manufacturers, and high-level information about research protocols and model analysis plans is posted publicly, but models are not fully transparent and replicable	Assessment models and all coding are open source, downloadable and customizable, allowing for full transparency and replicability	Methods are transparent but assessment scores are not replicable since they represent expert opinion	Assessment model is transparent; replicability cannot be evaluated without a formal assessment

- Although high-level information about research protocols and model analysis plans is posted publicly, ICER's assessment models lack full transparency and replicability. ICER has developed a program to facilitate the sharing of models with manufacturers (but not other stakeholders, such as patient groups). Manufacturers have had mixed experiences with these models, with some reporting redacted or locked data that prevented the models from being fully transparent and replicable.
- IVI's assessment models and all coding are open source, allowing users to download and customize the models with full transparency and replicability.

- NCCN's methods are transparent, but assessment scores are not replicable since they are based on expert opinion.
- The PPVF model is transparent, but replicability cannot be evaluated since no full assessments have been conducted.

D. Framework Evidence

Frameworks vary in the type of evidence they include in a value assessment (Table 7).

Table 7: Evidence

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
What Types of Evidence Are Used?	Health economic studies from literature review	Prospective randomized trial or pivotal trial used to support regulatory approval	Clinical trials from FDA approval for first indication	Many assessments are conducted pre-launch and hence rely largely on clinical trials, however, ICER has used other types of data (e.g., observational analyses, registries, patient surveys) when available	Clinical trials, real-world data	Expert opinion based on meta-analyses, RCTs, non-randomized trials, case reports, clinical experience	Meta-analyses, RCTs, real-world data studies
Is Non-published Evidence Allowed?	No	No	No	Yes	No	Yes	Yes
Can Manufacturer Submit Evidence?	No	No	No	Yes	No	Yes, process published on NCCN website	Not applicable



- ACC-AHA conducts a literature review for relevant health economic studies that include estimates of incremental cost per quality-adjusted life year. A validated and widely used tool, such as QHES (Quality of Health Economic Studies),¹⁷ is used to evaluate the quality of evidence.
- ASCO uses pivotal trials that supported regulatory approval or prospective randomized trials.
- DrugAbacus uses clinical trials from regulatory approval for a product's first indication.
- Many of ICER's assessments are conducted before a product has been approved, and hence rely largely on clinical trials. However, ICER has used other types of data, such as observational analyses, registries and patient surveys (generally in class reviews that include post-approval products). In addition, ICER's 2020-2023 framework outlines plans to improve and expand the use of real-world evidence (RWE) through collaborations with external organizations to generate new RWE as well as a new pilot program that will update previous assessments of drugs that were approved by the FDA under accelerated pathways after they have been on the market for 24 months. ICER also accepts manufacturer-submitted data. ICER uses its own methodology, the ICER Evidence Rating Matrix, to evaluate the evidence it uses.¹⁸
- IVI uses real-world data to inform patient preference, costs and baseline events rates (e.g., rate of disease progression, the rate at which patients discontinue treatment) in its OSVP models. In addition, to enhance the validity of the model, relative treatment effects are based on randomized controlled trial (RCT) data when possible.
- NCCN uses a broad range of evidence including meta-analyses, randomized and non-randomized trials, case reports and clinical experience for their guidelines, although the framework assessments are ultimately based on expert opinion. NCCN accepts externally submitted data and will consider non-published evidence from external sources. NCCN relies on panel members' assessment of the quantity, quality and consistency of evidence.
- The PPVF incorporates real-world data studies and allows non-published evidence in addition to meta-analyses and randomized clinical trials.

Framework Assessment Process

Only four frameworks have produced complete value assessments: ACC-AHA, ICER, IVI and NCCN; the other three frameworks have illustrative examples. The ASCO framework included several example assessments, but the software tool that will produce actual assessments has not been released. DrugAbacus is an online tool designed to allow users to “compare a company’s price [for a cancer drug] to one based on value”; beyond that there is no formal assessment. The PPVF scoring methodology for version 1.0 of the framework includes two partial case examples for how the framework can be applied, but no complete assessments have been released. A prototype of a PPVF-driven shared decision-making tool was released and validated, however.


Table 8: Framework Assessment Process

	ACC-AHA	ASCO	DrugAbacus	ICER	IVI	NCCN	PPVF
Assessments to Date	Five guidelines include “Cost and Value Considerations” section; only two include value statements for some of the recommendations	No complete assessments; ASCO included 10 hypothetical examples of the application of its framework in its initial draft framework and four in its updated framework	No complete assessments; illustrative tool includes 54 drugs approved from 2001-2015	43 assessment reports on 37 topics	Two assessments on two topics	55 guidelines include EBs; 43 guidelines include COPs	No complete assessments; methodology paper includes two partial hypothetical examples for how the framework could be applied; SDM tool created for advanced breast cancer
Selection Process for Future Evaluations	As guidelines are updated, cost-value consideration will be added when appropriate and feasible	Unknown at this time	No updates are planned	Selected by ICER; informed by horizon scan, analyses of the emerging drug pipeline and public input	Selected by IVI and its Board of Directors, informed by available evidence, multi-stakeholder input and IVI’s Scientific Advisory Panel	As clinical practice guidelines are updated, EBs and COPs will be added	Undetermined at this time



The process for selecting topics and conducting value assessments varies across the four frameworks that have produced complete assessments:

- When ACC-AHA is updating guidelines, an independent literature review for relevant health economic studies is conducted. Quality and potential for bias is assessed before the evidence is synthesized. When high-quality evidence exists that allows for the classification of value based on cost/QALY thresholds for specific treatments, a value statement for those treatments is included in the guidelines. A discussion of the evidence base is included in a separate section in the guidelines titled, “Cost and Value Considerations.” As of August 2019, five guidelines include this discussion section, and two of those guidelines include value statements for some of the treatment recommendations.
- ICER conducts a horizon scan and gathers stakeholder input to identify potential treatments for assessment. Assessment topics are announced and assigned to a public meeting of one of its three appraisal committees.^{19,20,21} ICER reaches out to manufacturers and patient groups involved in assessments to obtain input during the process as outlined in its engagement guides.^{22,23} Assessments include scoping, research protocol and model analysis plan, a draft report, a public meeting, a final report/meeting summary and a report-at-a-glance (which contains only high-level summary information). There are two public comment periods: one for scoping and one for the draft evidence report and voting questions. The appraisal committees vote on long-term value for money at the public meeting. ICER conducts “New Evidence Updates” for topic areas that it has previously reviewed to account for new information about an intervention that might “substantially change their original conclusions regarding comparative clinical effectiveness, long-term value for money, potential budget impact and/or health-benefit price benchmark.”²⁴ In addition, ICER recently updated its process for “Full Condition Updates,” which evaluate additional interventions for previously reviewed topics, and will now reassess whether new evidence has emerged for each topic review one year after the release of each Final Evidence Report. From January 2015 through February 2020, ICER has released 43 assessments (including two New Evidence Updates) on 37 topics.
- IVI’s assessment topics are selected by IVI and its board of directors, informed by available evidence, multi-stakeholder input and IVI’s Scientific Advisory Panel. The assessment process begins with the creation of a disease-specific model designed by a team of academic researchers with input from patient and provider groups as well as a clinical scientific advisor. Patients and patient groups are engaged from the beginning of the model development process to help discern research on patient preferences and to help identify participants to review preliminary findings for accuracy and representativeness. Once the preliminary model is complete, IVI publishes the model online and invites stakeholder feedback through a public comment period.



A third-party Technical Expert Panel then identifies which comments should be implemented by means of peer-review and a formal voting process. A revised model is then developed and re-released. Initial updates are planned within 12-18 months after public comment on the model. Subsequent updates will depend on new evidence generation, user need and resources. To facilitate transparency and improve user engagement and understanding, IVI releases the source code and a detailed technical summary of the model's underlying methodology. As of August 2019, IVI has released two disease-specific value models.

- NCCN's assessment process begins with notice that guidelines are being developed and/or updated. External parties may submit evidence, but only NCCN panel members are involved with the actual assessment. Panel members are listed on the NCCN website and in the corresponding guideline.²⁵ Each panel member uses the available evidence and his or her own experience to arrive at a numerical assessment (1-5) for each of the EBs; the final score for each block is the average of the panel members' assessments. EBs are released as part of NCCN guidelines and have been incorporated in 55 NCCN guidelines as of February 2020. In addition, panel members use the available evidence and their own experience to assign treatments to COPs within its guidelines. As of February 2020, COPs have been included in 43 NCCN guidelines.



Discussion

Value assessment tools can be one of many important inputs to complex decisions related to treatments. They have the potential for considerable impact on patients either through their use by patients and their doctors as shared decision-making tools or by payers to make coverage and reimbursement decisions.


Since the original landscape analysis was published in June 2016, health care payers and purchasers have become more familiar with value frameworks and have begun using assessments as an input in their decision-making. A 2019 Dymaxium survey of 534 payer organizations found that 76% of respondents had previously used an ICER report, 24% had used the NCCN EBs, 7% had used the ASCO framework, and 5% had used ACC-AHA.²⁶ Use of the DrugAbacus and PPVF frameworks were both under 2%; IVI was not included in the survey. In addition, several high-profile payers, including the Department of Veterans Affairs Pharmacy Benefits Management Services, CVS Caremark and the New York Medicaid program, among others, have publicly announced their use of ICER's analyses to inform their decision-making.^{27,28,29}

Given that frameworks are now being used more frequently, it is important to think critically about the implications of how these frameworks are constructed and applied. A reflection on the areas reviewed for this landscape update raises several cautions.

A. Lack of Patient-Centeredness

The patient is at the epicenter of health value, yet a broad range of the factors that patients care about are not quantitatively included in several of the frameworks. A comprehensive measure of patient-centered value would incorporate factors beyond effectiveness and side effects, such as quality of life, work productivity, caregiver burden, unmet need and burden of illness. Different patients will value these factors in different ways, so including a way for patients to give more weight to the factors they value most will result in a more meaningful value assessment for individual patients. Additionally, individual patients will respond to treatments differently — the average effectiveness and side effect response only represents the average patient. Including sensitivity analyses to capture the range of responses is important for a patient-centered value assessment.

As the field of value assessment has evolved and gained traction with key stakeholders, several resources have emerged to help foster and advance patient centrality in value assessment. The National Pharmaceutical Council's *Guiding Practices for Patient-Centered Value Assessment* include 28 specific guidelines to which frameworks should adhere in order to support optimal value for patients (see Appendix).³⁰ The National Health Council's *Patient-Centered Value Model Rubric*³¹ provides a tool to



help patients, providers, health systems and payers evaluate the patient centeredness of value assessment models and guide framework developers to incorporate meaningful patient engagement within their processes. In addition, some frameworks are collaborating with patient organizations and formally integrating patient recommendations into their frameworks and processes. For example, ICER is developing a Patient Engagement Program and as part of the third phase of the PPVF initiative, Avalere released a white paper with consensus-driven recommendations to encourage more patient orientation in value assessment framework methodologies.³² The Patient-Driven Values in Healthcare Evaluation (PAVE) Center, a collaboration among the University of Maryland School of Pharmacy, the National Health Council, patient community leaders, and payer and industry leaders, is working to expand patient engagement partnerships and “disseminate patient-driven value assessment principles and methods.”³³ Finally, a new report from the National Alliance of Healthcare Purchaser Coalitions’ Medical Director Advisory Council found that current value frameworks may not address employer/plan sponsor needs effectively because they do not include relevant impacts on employee productivity and performance, safety considerations, and total healthcare cost implications. Because employers are key purchasers of medical care in the United States, the Advisory Council put together a list of recommendations for including more employer-relevant content in value assessment.³⁴

These and other resources can help to evaluate current value assessment framework development and processes, identify shortcomings and advance best practices to promote value assessment that is meaningful to patients.

B. Lack of Transparency

To ensure the validity and credibility of value assessments, framework methodologies and models should be transparent and reproducible. Some frameworks rely on proprietary methods, which prevent end-users and researchers from replicating and validating an assessment’s output. The inability to contextualize or verify an assessment of value ultimately undermines its credibility and utility. IVI published the model methodology and source code for each of its OSVP tools, demonstrating that it is indeed possible to produce a fully transparent and reproducible value assessment framework.

C. Limited Evidence Base

Even a well-designed value assessment framework will be derailed if the evidence that feeds into the assessment framework is sub-optimal. Many of the assessments do not use the full range of available evidence, limiting their evidence base to clinical trials, and sometimes only a single clinical trial. All high-quality evidence, including real-world evidence, should be incorporated into assessments, and assessments should be updated regularly as new evidence becomes available.



D. Untested Methods

The field of value assessment is continuing to evolve. While some of the underlying methodologies in these frameworks are based on established and accepted standards, most involve new methodologies that are subject to limitations and may not have been fully tested or validated for use in health care decision-making in the United States. Conducting assessments is a complex and sophisticated undertaking, as evidenced by the sheer volume of guiding principles and practices for health technology assessments. Now that frameworks are being used to inform health care decision-making, it is critical that the underlying methodologies are sound and validated, and their potential impact on patients is understood.

E. Confusing Output

Value assessment framework outputs can be confusing and even misleading to end users in two ways. On one end of the spectrum, it may be unclear how to interpret and use an output, such as ASCO's net health benefit point system that cannot be compared across assessments. On the other end of the spectrum are outputs that suggest a false sense of precision and can be misused, such as ICER's health-benefit price benchmark or NCCN's EB scores. If health care decision-makers use this output without understanding the underlying uncertainty and potential range of valid value estimates, their decisions could be misinformed and erroneous at best, and harmful to the patient at worst.

F. Lack of a System-Wide Perspective

A system-wide perspective on value is missing from the frameworks. The focus is generally on drugs rather than on the broad range of treatments and health care services. For example, ICER conducted 38 reviews of prescription drug treatments from January 2015 through February 2020, but only five non-drug reviews in the same timeframe (all five were conducted between 2015 and 2017). Patient care involves many interrelated health care services, including physician visits, treatments such as drugs or surgeries, and hospital care. Moving to value-based health care requires a comprehensive focus on all health care components, rather than on one segment of health care. Value assessments should include consideration of all these interrelated services, and value assessments should be conducted for a broad range of these services.



Conclusion


This updated analysis highlights the ways in which value assessment frameworks have evolved in recent years. Although several of the frameworks have undergone important changes that positively advance the field of value assessment, there is still considerable need for good practices to guide rigorous, patient-centered value assessments.³⁵ Now that value assessment frameworks are being used more often in health care decision-making, it is critically important that health care decision-makers consider the strengths and limitations associated with each framework.

The value assessment frameworks reviewed in this landscape all have different purposes, methods, inputs and outputs. For each framework, the considerations related to patient-centeredness, transparency, robustness of the evidence base, validated methodologies, meaningful output and the breadth of assessment topics vary and should be taken into account by the user. There is no “best” framework and they all have strengths and limitations. Each will assess value differently, and there is no single answer to value. A conscientious user will rely on multiple frameworks and tools to assess value rather than looking to a single framework to inform health care decisions.




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Appendix

Guiding Practices for Patient-Centered Value Assessment


As our health care system continues to evolve from a volume-based system toward a value-based one, there is increasing interest in assessing value for all components of health care. Toward that end, a number of value assessment tools have emerged over the past year and more may emerge in the future. Value assessment tools are one of many important inputs to complex decisions related to treatments. They have the potential for considerable impact on patients either through their use by patients and their doctors as a shared decision-making tool or by payers to make coverage and reimbursement decisions, so maintaining patient-centricity in the assessment process is critical. Furthermore, assessment processes should not unduly delay patient access to innovation. Because this is a new and evolving area, it is important that good practices are established to guide meaningful value assessments.

Value encompasses the balance of benefits and costs experienced by patients and society over time. There is no single answer to a value assessment. The results will depend on the evidence, methods, models and assumptions underlying the assessment. Sensitivity analyses will introduce a range of possible results. Varying weights to reflect the preferences of and parameters facing the individual user (e.g., patient or payer) will further vary the results. Assessments should value continued scientific and medical progress by accounting for personalized medicine, the step-wise nature of progress, and the inherent value of innovation. Establishing good practices to guide value assessments can help ensure they are effective tools to support value in patient care and outcomes, rather than well-intentioned but flawed tools that impede it.


The National Pharmaceutical Council has developed *Guiding Practices for Patient-Centered Value Assessment* that include 28 specific elements, which are broken out into six key aspects of value assessments: the assessment process, methodology, benefits, costs, evidence and dissemination and utilization. *Guiding practices for budget impact assessment are outlined separately as budget impact is not a measure of value.*

Assessment Process

- I. Proposed assessment topic, process and timelines should be announced in advance to enable stakeholder participation and feedback. Announcing assessment plans in advance provides interested stakeholders with ample opportunity to set aside needed resources to provide input into upcoming assessments.

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- II. Interested stakeholders should be involved in the assessment process to represent all perspectives.^{1,2} Requesting comments from interested stakeholders at key points in the assessment process — such as the release of a draft report — ensures all perspectives are considered and provides the opportunity to fully vet the assessment. Provider and patient perspectives are especially important.
 - III. The scope of an assessment should be defined a priori and incorporate stakeholder input.^{3,4} Requesting comments from interested stakeholders on draft key questions and scope prior to beginning an assessment ensures all perspectives are considered and provides the opportunity to fully vet the planned scope and questions, and refine them where indicated.
 - IV. Public comment periods should be included, with sufficient time to review materials and submit comments, and with transparency around how comments are addressed by the convening body.^{5,6} Allowing sufficient time for interested stakeholders to review materials and prepare comments ensures that stakeholders are able to thoughtfully and comprehensively respond to the comment request. Providing transparency around how comments are addressed builds credibility and trust in the process.
 - V. Assessments should be regularly reviewed and updated to keep pace with and account for medical innovation. There should be a continuous open process for stakeholders to request a timely review of an assessment to account for new technology or other changes in the evidence base.⁷ Changes in technology and the evidence base can cause an assessment to become outdated, and those outdated results could adversely impact patient care and outcomes. Having a regular review cycle, along with a process for requesting an updated review when indicated, can ensure assessment results remain current and provide the timeliest information to guide shared decision-making and patient care.

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- VI. Sufficient time, staff and resources should be dedicated to support a thorough and robust assessment process. Considerable infrastructure and resources are needed to support a thorough and robust assessment process. Attempting to conduct assessments without sufficient time, staff and resources can lead to assessments of lesser quality, which could adversely impact patient care and outcomes.

Methodology

- VII. Value assessments should focus broadly on all aspects of the health care system, not just on medications.^{8,9,10} Focusing on one component of an interconnected system does not provide a complete perspective on the system. Medications are one component of the health care system. Focusing only on medications, and excluding the rest of the health care system (e.g., procedures, diagnostic tests, hospitalizations, office visits), will result in an incomplete assessment.
- VIII. Methods should be based on established health economic methodologies, consistent with accepted standards. Health economic assessment is a very complex and sophisticated undertaking and many bodies of work and years of debate have shaped the methods. Following accepted methodological standards (e.g., ISPOR Good Practices, Cochrane)^{11,12,13,14} is necessary to produce a meaningful and credible assessment of value.
- IX. Methods, models and assumptions should be transparent and assessment results should be reproducible. To build credibility and trust in an assessment, the methods, models (including all calculations) and assumptions included in the assessment should be transparent to interested stakeholders,^{15,16} and they should be able to reproduce the assessment results on their own.

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- X. Base case assumptions must represent reality.¹⁷ As the base case is the underpinning for all assessment results, it is critical that the assumptions inherent in the base case are realistic and accurate. Value assessment includes many assumptions, and these assumptions will drive the final results; unrealistic assumptions will drive unrealistic results.
 - XI. Sensitivity analyses should be performed, taking into account input from external stakeholders. Where sensitivity analyses result in material changes to the interpretation of the results, a focused discussion should be included.^{18,19} Performing sensitivity analyses around key assumptions will identify how results could vary in differing scenarios, and will generate a range of potential results. The implications for the user may vary across this range, so clear guidance will be needed to help them understand which assumptions are driving the differences and why.
 - XII. Weights should be included to accommodate varying user preferences. The user should be able to adjust the assessment assumptions and parameters to accommodate individual preferences for different outcomes and factors (e.g., patient preferences for clinical benefit vs. side effects) and make adjustments to represent different scenarios (e.g., payer ability to vary the population).

Benefits

- XIII. The measurement of value should include a broad array of factors that are important to patients and society.^{20,21} Patients and society value a variety of factors such as survival, quality of life, the ability to participate in daily activities, caregiver burden, worker productivity, short-term disability, unmet need for diseases with limited or no treatments, burden of disease and innovation. Not including these factors in a value assessment provides an incomplete picture of a treatment's value.
- XIV. Clinical benefits and harms should be incorporated in a manner that recognizes the heterogeneity of treatment effect rather than the average response.²² Patients respond to treatments differently. Building flexibility into an assessment to account for this heterogeneity can make the assessment more meaningful for the full spectrum of patients.

17. Drummond M, Schwartz JS, et al. Principle 5. 251.


18. Drummond M, Schwartz JS, et al. Principle 8. 252.

19. Luce BR, Drummond MF, et al. Principle 11. 436.

20. Luce BR, Drummond MF, et al. Principle 7. 434.

21. Drummond M, Schwartz JS, et al. Principle 6. 252.

22. Luce BR, Drummond MF, et al. Principle 10. 436.

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- XV. The time horizon for value should be long-term, ideally lifetime.²³ Many of the benefits of treatments, such as avoided events (e.g., heart attacks), show up in the longer term. To capture the full value of a treatment, the time horizon for clinical and care value should be long enough to capture these benefits, ideally covering a patient's lifetime.

Costs


- XVI. All health care costs and cost offsets should be included.²⁴ Treatments may have up-front costs that lead to long-term improvements in patient health. Those improvements may have “cost offsets,” or reductions in resource needs, such as reduced hospitalizations. By including both the costs and cost offsets, the full value of a treatment can be assessed. Only considering the treatment costs, but not the potential cost offsets, would lead to an incomplete assessment of value.
- XVII. The time horizon for costs should be long enough to incorporate the benefits of the treatment and the lower costs of medications when they become generic. Many of the cost offset benefits of treatment, such as avoided hospitalizations, show up in the longer term. To measure the full value of a treatment, the time horizon for costs should be long enough to capture these cost offsets,²⁵ and to account for the lower costs of medications when generics and biosimilars are introduced.
- XVIII. Costs should be representative of the net price most relevant to the user.²⁶ Costs are a driving component of a value assessment, and care should be taken to ensure that costs are as representative of actual price as possible in order to achieve an accurate assessment. For biopharmaceuticals, following International Society for Pharmacoeconomics and Outcomes Research (ISPOR) good research practices for measuring drug costs can help achieve this objective. Additionally, the included costs should be those most relevant for the user; if the user is the patient, measuring their copay will be more meaningful than measuring what their plan pays.

23. Mathes T, Jacobs E, Morfeld JC, Pieper D. Methods of international health technology assessment agencies for economic evaluations – a comparative analysis. *BMC Health Services Research* 2013, 13:371.

24. Drummond M, Schwartz JS, et al. Principle 7. 252.

25. Hay JW, Smeeding J, Carroll NV, et al. Good research practices for measuring drug costs in cost effectiveness analyses: issues and recommendations: the ISPOR drug cost task force report – Part I. *Value Health* 2010;13:3-7. Recommendation 5. 6.

26. Hay JW, Smeeding J, et al. Recommendations 1, 4, 8. 6.

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- XIX. Thresholds should be developed in a transparent manner, may vary by population and disease, and should undergo a multi-stakeholder evaluation process. Since thresholds are an emerging area, their development and application should be transparent²⁷ and subject to a multi-stakeholder evaluation process reflecting societal values related to disease conditions and innovation. No single threshold can or should be universally applicable; thresholds are likely to vary by population and disease.

Evidence

- XX. Evidence should be identified in a systematic, transparent and robust manner. To maximize credibility and trust in the assessment process, the manner in which evidence is identified for the assessment should be systematic, transparent and robust.
- XXI. Stakeholders should be given the opportunity to submit relevant evidence, such as clinical trial and real-world evidence beyond the published literature.²⁸ Stakeholders may have pertinent evidence that is not available in the published literature. To ensure the evidence base is as comprehensive as possible, stakeholders should be given the opportunity to submit this evidence for consideration.
- XXII. Best available evidence should be used for the assessment.^{29,30} Understanding a treatment's impact on patient-centered outcomes is critical in an assessment of value. In certain circumstances, only randomized clinical trial evidence may be available. In others, real-world evidence may provide an additional understanding of how a treatment is used for typical patients, and its comparative assessment to alternative patient care options. Both high quality clinical trial and real-world evidence should be considered in any value assessment.
- XXIII. Accepted methods should be used to assess quality of evidence, certainty of evidence and conflicting evidence.³¹ The results of an assessment depend on the evidence that underlies it. Evidence can be of varying quality and certainty, and the findings from individual studies can conflict with each other. To produce a meaningful and credible assessment, accepted methods should be used to evaluate quality and certainty of evidence and to determine how to handle conflicting evidence.

27. Drummond MF, Schwartz JS, et al. Principle 15. 256.

28. Drummond MF, Schwartz JS, et al. Principle 10. 254.

29. Drummond MF, Schwartz JS, et al. Principle 11. 254.

30. Luce BR, Drummond MF, et al. Principle 8. 435.

31. Luce BR, Drummond MF, et al. Principle 9. 435.



- XXIV. Where evidence synthesis is warranted, formal analysis should be conducted, in accordance with accepted methodologies. The process of synthesizing evidence is a complex one. When there is a need to combine multiple sources of quantitative evidence, accepted methodologies should be followed in order to ensure a meaningful and credible assessment.
- XXV. Subjective evidence should be used minimally, if at all, and its inclusion should be clearly labeled.³² In situations where high-quality evidence is lacking, subjective evidence, such as expert opinion, might be considered. Expert opinion may be biased by the expert's experiences or beliefs, making it less reliable. As such, it should be treated as lesser quality evidence and its use should be minimized. Subjective evidence should be transparently labeled and the user should be made aware of the potential limitations.

Dissemination and Utilization


- XXVI. Assessment results should be presented in a manner that is simple for the user to interpret and apply.³³ The process and output of a value assessment can be complicated. Presenting the results in a manner that can be easily understood and applied by the user is critical for the value assessment to achieve its intended impact. Developing educational materials to assist the user in interpretation and application is recommended.
- XXVII. Value assessment should clearly state the intended use and audience to avoid misuse.³⁴ With the broad interest in value assessments, there comes a risk that assessment results will be misused by an unintended audience. For example, a value assessment designed for payers may not be appropriate for shared decision-making between patients and their doctors, and vice versa. Safeguards against misuse should be incorporated, such as creating a guidance statement that is explicit about how assessments should (and should not) be used.
- XXVIII. Press releases should only be issued for final assessments, include limitations of the assessment, and highlight areas where sensitivity analyses result in material changes to the interpretation of the results.³⁵ A draft value assessment is, by definition, a preliminary assessment. The final assessment incorporates the benefit of stakeholder input and is often materially different than

32. Balshem H, Helfand M, et al. GRADE guidelines: 3. Rating the quality of evidence. *Journal of Clinical Epidemiology* 2011;64:401-406.

33. Drummond MF, Schwartz JS, et al. Principle 14. 255.

34. Donaldson MS, Sox HC. Guiding Principle 2. 53.

35. Health News Review. Story Review Criteria. Criteria 4. <http://www.healthnewsreview.org/about-us/review-criteria/>. Accessed January 18, 2016.



the draft assessment. Issuing a press release for a draft assessment calls media attention to preliminary results and encourages widespread reporting of these preliminary findings. In the past, the media has reported on draft assessments and paid little attention to the final assessments, with the end result that the preliminary results are the ones that remain top of the public's mind.

Guiding Practices for Budget Impact Assessment

The ISPOR Budget Impact Analysis Good Practice II Task Force defines budget impact analysis (BIA) as an estimation of "...the expected changes in expenditure of a health care system after the adoption of a new intervention."³⁶ A BIA is a measure of resource use, not a measure of value. It can inform the user about what they are paying, but not about what they are paying for – value. Labeling a BIA as a measure of value is inaccurate and misleading; the label for a BIA should make clear that it is an assessment of budget impact, not of value.


BIAs have the potential to have considerable impact on patients through their use by payers to make coverage and reimbursement decisions. The way they are collectively used has the potential to have considerable impact on society – for example, disincentivizing innovation in highly prevalent diseases or not giving treatments with greater clinical benefit a larger share of the available budget. Given this potential impact, it is important to establish methodologic best practices. Recommended guiding practices are outlined below.

- I. Budget impact assessments should examine all aspects of the health care system, not just medications.³⁷ Use of medications will have an impact on the use of other health care services (e.g., increased laboratory testing, decreased hospitalizations) and hence an impact on other condition-related costs. Considering only the medication cost in a BIA will result in an incomplete and inaccurate assessment.
- II. Budget impact assessments should be separate from value assessments.³⁸ A BIA is a measure of resource use, not a measure of value. It can inform the user about what they are paying, but not about what they are paying for – value. This is reinforced in the Academy of Managed Care Pharmacy's (AMCP) draft format for formulary submissions, version 4.0, which says, "Budget

36. Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis – principles of good practice: report of the ISPOR 2012 budget impact analysis good practice II task force. *Value in Health* 2014;17:5-14.

37. Sullivan SD, Mauskopf JA, et al. Impact on Other Costs. 8.

38. Sullivan SD, Mauskopf JA, et al. Reporting BIAs Alongside CEAs. 13.



impact models are not intended to establish the overall value of health care technologies because they do not include the full impact of the technology on clinical and patient outcomes.”³⁹ Attempting to combine the two concepts causes confusion and obscures the individual results from the two assessments.


- III. Budget impact assessments should include time frames that are long enough to incorporate the benefits of the innovation⁴⁰ and the lower costs of medications when they become generic. Many of the cost-offset benefits of treatment, such as avoided hospitalizations, show up in the longer term. To fully measure the budget impact of a treatment, assessments should include a time horizon for costs that is long enough to capture these cost offsets, and to account for the lower costs of medications when they become generic.
- IV. Budget impact assessments should include realistic estimates regarding the uptake rate. Stakeholders may have done extensive assessments of potential uptake and should be given the opportunity to submit their results. A sensitivity analysis of different uptake rates should be conducted.⁴¹ Many factors will influence the uptake rate, such as: the approved indication, utilization management restrictions, induced demand from previously untreated patients, and changes in provider patterns of use. Stakeholders who have conducted assessments of potential uptake should be given the opportunity to share their results to help inform the estimate. Sensitivity analysis should be performed to examine the impact of different assumptions about the size of the treated population and ranges should be reported.
- V. Budget impact assessments should acknowledge the considerable uncertainty in the inputs by incorporating sensitivity analyses and reporting ranges around estimates.⁴² There is considerable uncertainty in all inputs for a BIA and these will vary by health care system. For all key inputs, sensitivity analysis should be performed to examine the impact of varying assumptions and ranges should be reported.

39. AMCP Format for Formulary Submissions, Version 4.0 (draft), <http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=20528>. Accessed January 19, 2016.

40. Sullivan SD, Mauskopf JA, et al. Time Horizon. 9.

41. Sullivan SD, Mauskopf JA, et al. Eligible Population. 8.

42. Sullivan SD, Mauskopf JA, et al. Uncertainty and Scenario Analyses. 9

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- VI. A BIA is simply an assessment of budget impact, and should not be judged against artificial affordability caps. A BIA is an estimation of a health care system's expenditure changes from a new treatment, not an assessment of whether the health care system can afford the new treatment. Given the uncertainty inherent in BIA estimates, and the system-specificity of affordability concerns, it is not the role of a BIA to make artificial determinations of affordability.
- VII. Assessments of ways to address budget impact concerns should include all relevant stakeholders and consider all approaches.⁴³ If there are stakeholder concerns that a treatment that society values may be unaffordable, all interested stakeholders (e.g., patients, providers, employers, health plans) should be involved in considering alternative approaches for achieving affordability (e.g., alternative financing models, utilization management, reinsurance).

43. Drummond MF, Schwartz JS, et al. Principle 7. 252. 8.



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